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EXAMINER

YANG, NELSON C

ART UNIT PAPER NUMBER

1641

DATE MAILED: 06/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/911,253

Applicant(s)

VIRTANEN, JORMA

Examiner

Nelson Yang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 34-80 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 and 44-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/23/01.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of group III, claims 34-43 in the reply filed on March 21, 2005 is acknowledged.
2. Claims 1-20, 44-80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 21, 2005.

### *Drawings*

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the 'radiation inlet', 'radiation outlet', 'wave guide inlet', and 'wave guide outlet' must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet"

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pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Specification*

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the terms 'radiation inlet', 'radiation outlet', 'wave guide inlet', and 'wave guide outlet' could not be found in the specification.

### *Claim Objections*

5. Claim 43 is objected to because of the following informalities: claim 43 appears to have been improperly labeled as a withdrawn claim. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 34-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 34 recites the limitation 'said wave guide inlet' in the fifth line and 'said wave guide outlet' in the seventh line. There is insufficient antecedent basis for these limitations in the claim.

9. The remaining claims are rejected due to their dependence on an indefinite claim.

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant fails to disclose the presence of radiation or wave guide inlets and radiation or wave guide outlets in the original disclosure.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 34-35, 38-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Mian et al [US 6,319,469].

With respect to claim 34, Mian et al teach a disk comprising sample inlet ports, fluid microchannels, reagent reservoirs, reaction chambers, detection chambers, and sample outlet ports (column 3, lines 35-42). Specific sites on the disk also comprise elements that allow fluids

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to be analyzed, including thermal sources, light sources, as well as detectors for these effectors (column 3, lines 50-57). Fluorescence is coupled back into a waveguide on the disk, thereby increasing the efficiency of detection. Mian et al also teach a radiation inlet and radiation outlet (fig. 16). In these embodiments, the optical component preceding the detector can include a dispersive element to permit spectral resolution. Fluorescence excitation can also be increased through multiple reflections from surfaces in the device whenever noise does not scale with path length in the same way as with signal (column 21, lines 49-57). Mian et al further teach that the sample chamber can be a planar waveguide, wherein the analyte interacts on the face of the waveguide and light absorbance is the result of attenuated total internal reflection (i.e., the analyte reduces the intensity source light if the analyte is sequestered at the surface of the sample chamber, using, for example, specific binding to a compound embedded or attached to the chamber surface (column 22, lines 8-35).

14. With respect to claim 35, Mian et al teach an embodiment where an immobilized antibody is presented to a sample to be tested for the antigenic analyte specific for the immobilized antibody. A second antibody, specific for a different epitope of the same antigen is subsequently bound, making a "sandwich" of the antigen between the two bound antibodies. In such assays, the second antibody is linked to a detectable moiety, such as a radiolabel or fluorescent label, or an enzymatic or catalytic functionality. For example, horseradish peroxidase or alkaline phosphatase are used to produce a color change in a substrate, the intensity of which is related to the amount of the second antibody bound in the sandwich (column 35, line 60 – column 36 – line 9).

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15. With respect to claim 38, Mian et al teach that specific sites on the disk comprise elements that allow fluids to be analyzed, including thermal sources, light sources, as well as detectors for these effectors (column 3, lines 50-57).

16. With respect to claim 39, Mian et al teach a multiplicity of microsystems on a disk, with reaction chambers (column 4, lines 38-55, figs. 1A-1C), and that hybridization/denaturation analysis can be performed with a battery of precharacterized test probes, where hybridization and denaturation are multiplexed, using probes detectably labeled with different detectable labels so that each probe can be identified (column 45, lines 5-12).

17. With respect to claim 40, fluorescence is coupled back into a waveguide on the disk, thereby increasing the efficiency of detection (column 21, lines 49-57).

18. With respect to claim 41, the disk contains resident software (column 35, lines 50-60).

19. With respect to claim 42, the disk is an optical disk (column 4, lines 10-15).

20. With respect to claim 43, the disk appears to be coated with hydrophilic coatings such as silanes and siloxanes (column 14, lines 59-62).

### *Claim Rejections - 35 USC § 103*

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. Claims 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mian et al [US 6,319,469] in view of Rothschild et al [US 5,986,076].

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With respect to claim 36, Mian et al teach an assay system comprising a first immobilized antibody specific for an analyte and a second antibody specific for the analyte, where the second antibody is attached to a detectable moiety (column 35, line 61 – column 36, line 9). Mian et al do not teach that the detectable moiety is attached to a photocleavable spacer bound to the exterior surface of the waveguide.

Rothschild et al, however, do teach detectable moieties bound to the surface of an article by photoreactive moieties (column 13, lines 10-17). Rothschild et al further teach that this allows for the controlled release of the substrate into a medium (column 13, lines 8-10), and also teach that since the detectable moiety, the reactive group and the photoreactive moieties are chemically separate, the properties of each can be adjusted to meet the requirements for detection of a particular substrate (column 25, lines 30-37).

Therefore, it would have been obvious in the system of Mian et al for the detectable moieties to be bound to photocleavable moieties, as suggested by Rothschild et al, in order to allow for the controlled release of the substrate into the medium, and to keep the detectable moiety, the reactive group and the photoreactive moieties chemically separate so that the properties of each can be adjusted to meet the requirements for detection of a particular substrate.

### ***Conclusion***

23. No claims are allowed.
24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang  
Patent Examiner  
Art Unit 1641



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06/03/05